a first container, and a composition comprising an active agent contained within said container;

wherein the composition is effective for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease, and the active agent in said composition comprises HGF;

a second container comprising a pharmaceutically-acceptable buffer; and

instructions for using the HGF to treat vascular insufficiency or limb ischemia secondary to arterial occlusive disease.

11. (Amended) A pharmaceutical composition for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease comprising hepatocyte growth factor (HGF) in a pharmaceutical carrier acceptable for intravenous, intraarterial or infusion administration.

13. (Amended) The pharmaceutical composition of Claim 11, wherein said HGF is recombinantly produced HGF.

REMARKS

Independent Claims 8, 10, and 11 have been amended to recite that the composition recited in each of the respective claims is effective for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease. Claim 9 has been amended to recite that HGF is administered to a mammal to treat vascular insufficiency or limb ischemia secondary to arterial occlusive disease. Support for the requested amendments to Claims 8, 9, 10, and 11 is found throughout the specification, e.g., at page 6, lines 25-27 and in the Example. No question of new matter arises and entry of the amendment is respectfully requested.

Rejection under 35 U.S.C. §112, second paragraph

On page 2 of the Office Action, the Examiner has rejected Claim 13 as being indefinite because the Examiner is unsure if the HGF is produced recombinantly or if the HGF has itself been recombined. In response, Applicants have amended Claim 13 to recite that the HGF is recombinantly produced. Applicants submit that as amended, Claim 13 is sufficiently definite. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. §102(b)

On page 3 of the Office Action, Claims 8-12 have been rejected under 35 U.S.C. §102(b) as being anticipated by Rosen et al. (1993) ("Rosen"). Applicants respectfully traverse this rejection in view of the following remarks.

In particular, Applicants respectfully direct the Examiner's attention to the amendments to independent Claims 8, 10, and 11. Applicants respectfully submit that the amendments to Claims 8, 10, and 11 patentably distinguish the present invention over the cited prior art reference. In particular, Claims 8, 10, and 11 have been amended to recite that each of the respective compositions claimed in Claims 8, 10, and 11 is effective for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease. Applicants respectfully submit that Rosen does not teach a composition for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease as claimed in Claims 8, 10, and 11. Accordingly, Applicants respectfully submit that amended independent Claims 8, 10, and 11 are patentably distinguishable over Rosen. As such, Claims 8, 10, and 11 are non-obvious and patentable.

Applicants respectfully submit that the independent claims in this application, as amended, define inventions that are not taught or suggested within Rosen. Accordingly,

Applicants respectfully request that this rejection be reconsidered and withdrawn and that these amended claims be passed to allowance, together with all of the claims dependent therefrom.

Rejection under 35 U.S.C. §102(b)

On page 2 of the Office Action, Claims 8-12 have been rejected under 35 U.S.C. §102(b) as being anticipated by Zarnegar et al. ("Zarnegar"). Applicants respectfully traverse this rejection in view of the following remarks.

In particular, Applicants respectfully direct the Examiner's attention to the amendments to independent Claims 8, 10, and 11. Applicants respectfully submit that the amendments to Claims 8, 10, and 11 patentably distinguish the present invention over the cited prior art reference. In particular, Claims 8, 10, and 11 have been amended to recite that each of te respective compositions claimed in Claims 8, 10, and 11 is effective for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease. Applicants respectfully submit that Zarnegar does not teach a composition for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease as claimed in Claims 8, 10, and 11. Accordingly, Applicants respectfully submit that amended independent Claims 8, 10, and 11 are patentably distinguishable over Zarnegar. As such, Claims 8, 10, and 11 are non-obvious and patentable.

Applicants respectfully submit that the independent claims in this application, as amended, define inventions that are not taught or suggested within Zarnegar. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn and that these amended claims be passed to allowance, together with all of the claims dependent therefrom.

Rejection under 35 U.S.C. 35 U.S.C. §102(b)

On page 4 of the Office Action, the Examiner has rejected Claims 8-12 over Grant et al. (1993) ("Grant"). Applicants respectfully traverse this rejection in view of the following remarks.

In particular, Applicants respectfully direct the Examiner's attention to the amendments to independent Claims 8, 10, and 11. Applicants respectfully submit that the amendments to Claims 8, 10, and 11 patentably distinguish the present invention over the cited prior art reference. In particular, Claims 8, 10, and 11 have been amended to recite that each of the respective compositions claimed in Claims 8, 10, and 11 is effective for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease. Applicants respectfully submit that Grant does not teach a composition for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease as claimed in Claims 8, 10, and 11. Accordingly, Applicants respectfully submit that amended independent Claims 8, 10, and 11 are patentably distinguishable over Grant. As such, Claims 8, 10, and 11 are non-obvious and patentable.

Applicants respectfully submit that the independent claims in this application, as amended, define inventions that are not taught or suggested within Grant. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn and these amended claims be passed to allowance, together with all of the claims dependent therefrom.

Rejection under 35 U.S.C. §102(b)

On page 4 of the Office Action, Claims 8-12 have been rejected under 35 U.S.C. §102(b) as being anticipated by Bussolino et al. (1992) ("Bussolino"). Applicants respectfully traverse this rejection in view of the following remarks.

Applicants respectfully direct the Examiner's attention to the amendments to independent Claims 8, 10, and 11. Applicants respectfully submit that the amendments to Claims 8, 10, and 11 patentably distinguish the present invention over the cited prior art reference. In particular, Claims 8, 10, and 11 have been amended to recite that each of the respective compositions claimed in Claims 8, 10, and 11 is effective for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease. Applicants respectfully submit that Bussolino does not teach a composition for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease as claimed in Claims 8, 10, and 11. Accordingly, Applicants respectfully submit that amended independent Claims 8, 10, and 11 are patentably distinguishable over Bussolino. As such, Claims 8, 10, and 11 are non-obvious and patentable.

Applicants respectfully submit that the independent claims in this application, as amended, define inventions that are not taught or suggested within Bussolino. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn and these amended claims be passed to allowance, together with all of the claims dependent therefrom.

Rejection under 35 U.S.C. §103(a)

On page 5 of the Office Action, the Examiner has rejected Claims 6-7 under 35 U.S.C. §103(a) as being obvious over Rosen, Zarnegar, Grant, or Bussolino in view of Godowski et al. (1994) ("Godowski").

Initially, Applicants note that Claims 6-7 are not pending in the present application. In this regard, Applicants respectfully request that this rejection be withdrawn.

However, regardless of the claims that the Examiner intended to reject, Applicants submit that Rosen, Zarnegar, Grant, and Bussolino do not teach or suggest the invention claimed in

amended independent Claims 8, 10, and 11. More specifically, independent Claims 8, 10, and 11 have been amended to recite that each of the respective compositions is effective for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease. Applicants respectfully submit that neither Rosen, Zarnegar, Grant, nor Bussolino teach a composition for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease as claimed in amended Claims 8, 10, and 11. Accordingly, Applicants respectfully submit that Rosen, Zarnegar, Grant, and Bussolino do not teach or suggest the presently claimed invention.

Furthermore, Applicants submit that the teachings of Godowski do not make up for the deficiencies of Rosen, Zarnegar, Grant, and Bussolino. As such, the combination of the Examiner's references would not result in the invention as presently claimed. Thus, the present invention is not obvious over Rosen, Zarnegar, Grant, or Bussolino in view of Godowski.

CONCLUSION

In light of the above, Applicants believe that this application is now in condition for allowance and therefore request favorable consideration.

If any points remain in issue which the Examiner feels may be best resolved through a

personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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MARKED-UP COPY OF AMENDED CLAIMS

8. (Amended) An article of manufacture, comprising:

a container; and

[a label on said container; and]

a composition comprising an active agent contained within said container;

wherein the composition is effective for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease [enhancing angiogenesis, the label on said container indicates that the composition can be used for enhancing angiogenesis], and the active agent in said composition comprises HGF.

9. (Amended) The article of manufacture of claim 8 further comprising instructions for administering the HGF to a mammal to treat vascular insufficiency or limb ischemia secondary to arterial occlusive disease [enhance angiogenesis].

10. (Amended) A kit, comprising:

a first container, [a label on said container,] and a composition comprising an active agent contained within said container;

wherein the composition is effective for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease [enhancing angiogenesis, the label on said container indicates that the composition can be used for enhancing angiogenesis], and the active agent in said composition comprises HGF;

a second container comprising a pharmaceutically-acceptable buffer; and

instructions for using the HGF to treat vascular insufficiency or limb ischemia secondary to arterial occlusive disease [enhance angiogenesis].

11. (Amended) A pharmaceutical composition for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease [enhancing angiogenesis] comprising hepatocyte growth factor (HGF) in a pharmaceutical carrier acceptable for intravenous, intraarterial or infusion administration.

13. (Amended) The pharmaceutical composition of Claim 11, wherein said HGF is [recombinant] recombinantly produced HGF.